JUN 13 2014

K140312

SECTION 5 – 510(k) SUMMARY

EV1000™ Clinical Platform with ClearSight™ Finger Cuffs 510(k)	
510(k) Submitter	Edwards Lifesciences, LLC
Contact Person	Renate A. MacLaren, Ph.D.
Date Prepared	February 6, 2014
Trade Name	EV1000 Clinical Platform™ with ClearSight™ Finger Cuffs or ClearSight™ System
Common Name	Non-Invasive Blood Pressure Measurement System
Classification Name	System, Measurement, Blood-Pressure, Non-Invasive (21 CFR 870.1130, Product Code DXN Plethysmograph, Impedance (21 CFR 870.2770, Product Code DSB)
Regulation Class/Product Code	Class II DXN, DSB
Predicate Device(s)	ccNexfin Model 2 K122381 (cleared April 22, 2103) EV1000 Clinical Platform K110597 (cleared June 14, 2011)
Device Description	The EV1000 Clinical Platform with ClearSight Finger Cuffs is a non-invasive monitor that enables the continuous assessment of a patient's hemodynamic function based on the scientific method of Peňàz – Wesseling. The device measures continuous non-invasive blood pressure (Systolic, Diastolic, and Mean Arterial Pressure) and pulse rate. Cardiac Output and other hemodynamic parameters are derived from the blood pressure waveform. The EV1000 ClearSight™ System consists of a monitor, a pump-unit, a pressure controller that is worn on the wrist, and ClearSight Finger cuffs. The EV1000 Pump-unit receives incoming signals from the pressure controller and the finger cuffs. The algorithms embedded in the Pump-Unit and the pressure controller process signals from the finger cuffs and provide parameter calculations. The EV1000 Monitor is connected to the Pump-Unit via an Ethernet cable, and the Pump-unit is connected to the pressure controller via a RS485 port. The monitor is a touchscreen panel PC with a graphical user interface (GUI). The monitor displays the measured and calculated parameters from the Pump-Unit.

Indications for Use/Intended Use	The EV1000 Clinical Platform and the ClearSight™ Finger Cuffs are indicated for patients over 18 years of age in which the balance between cardiac function, fluid status, and vascular resistance needs continuous assessment. In addition, the non-invasive system is indicated for use in patients with co-morbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The EV1000 Clinical Platform and the ClearSight™ finger cuffs noninvasively measures blood pressure and associated hemodynamic parameters.
Comparative Analysis	Verification and Validation testing was conducted to compare the performance and functionality of the EV1000 Clinical Platform with ClearSight Finger Cuffs to the predicate device. The testing included side-by-side bench testing and a clinical study. The EV1000 Clinical Platform with ClearSight Finger Cuffs was shown to be safe, effective, and substantially equivalent to the predicate device (ccNexfin) for its intended use in hospitals and other appropriate clinical environments.
Functional/ Safety Testing	The EV1000 Clinical Platform with ClearSight Finger cuffs has successfully passed functional and performance testing, including software verification and validation, mechanical and electrical testing, and bench studies. In addition, a clinical study demonstrated that the device is substantially equivalent to the cited predicate device
Conclusion	The EV1000 Clinical Platform with ClearSight Finger cuffs has been shown to be safe, effective, and is substantially equivalent to the predicate ccNexfin for its intended use in hospitals and other appropriate clinical environments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-0002

June 13, 2014

Edwards Lifesciences, LLC
Renate Maclaren, Ph.D.
Senior Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K140312
Trade/Device Name: EV1000 Clinical Platform with Clearsight finger cuff or Clearsight system
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Monitoring Device
Regulatory Class: Class II
Product Code: DXN, DSB
Dated: May 9, 2014
Received: May 12, 2014

Dear Dr. Maclaren,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): **K140312**

Device Name: EV1000 Clinical Platform Non-Invasive (NI) and ClearSight™ Finger Cuffs or ClearSight™ System

Indications For Use:

The EV1000 Clinical Platform and the ClearSight™ Finger Cuffs are indicated for patients over 18 years of age in which the balance between cardiac function, fluid status, and vascular resistance needs continuous assessment. In addition, the non-invasive system is indicated for use in patients with co-morbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The EV1000 Clinical Platform and the ClearSight™ finger cuffs noninvasively measures blood pressure and associated hemodynamic parameters.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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